REMARKS/ARGUMENTS

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species. More specifically, Applicant is required to define each of a species of solubilized therapeutic agent, a species of co-surfactant, a species of oil and a species of nonionic surfactant.

Applicant hereby provisionally elects rapamycin as the therapeutic agent, sorbitan monooleate as the co-surfactant, neutral oil as the oil, and polyoxyethylene sorbitan monooleate as the nonionic surfactant. Applicant's provisional election is made with traverse.

Applicants respectfully traverse the restriction requirement for the following reasons.

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct. 37 C.F.R. §1.141-142. Without independence and distinctness, a restriction requirement is unauthorized.

Further, the Examiner apparently relies on separate subclass classifications in taking the position that the claimed subject matter has been established as separate distinct in the pharmaceutical arts. It is respectfully submitted that reliance on classification does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. Rather, the classification system is an aid in finding and searching for patents. A classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more that growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.S. § 121.

Also, it is submitted that the searching burden for the generic claim is not unduly extensive. Claims of similar scope are routinely searched by the Patent Office. Requiring restriction to a single species effectively prevents Applicant from obtaining any generic protection for his invention.

In addition to the above arguments, it is respectfully pointed out that upon allowance of the examined species claims, the generic or linking claims (e.g., Claim 11.) must also be

examined in whole, not in part (see MPEP 809, "The linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn", see also MPEP 803.02, "The prior art search will be extended to the extent necessary to determine the patentability of the Markush-type claim").

For the above stated reasons it is requested that the restriction requirement be withdrawn. Action on the merits is respectfully requested.

Respectfully submitted,

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